DEPARTMENT OF VETERANS AFFAIRS
Justification and Approval
For
Other Than Full and Open Competition

1. Contracting Activity: Department of Veterans Affairs, Network Contracting Office 16, Michael E. DeBakey VA Medical Center (MEDVAMC), Houston, Texas.

2. Nature and/or Description of the Action Being Processed:

Request approval to limit competition to a single manufacturer/source. This acquisition will result in the award of a firm fixed price contract for commercial items.

This transaction is for the set-up of an Consignment agreement with the vendor Boston Scientific for the ongoing purchase of Watchman left atrial appendage closure devices for the remainder of FY17 (October 1, 2016 through September 30, 2017). Watchman devices are used in the Electrophysiology Lab during emergency surgeries.

The Watchman consists of a delivery catheter and a device that is permanently implanted in the left atrial appendage (LAA) of the heart. The device prevents LAA blood clots from entering the bloodstream and potentially causing a stroke. It is made of a self-expanding, nickel-titanium (Nitinol) frame with an attached woven plastic cap.

The Watchman is used in patients who have atrial fibrillation (AFib) not related to heart valve disease. In AFib, the two upper chambers (atria) of the heart no longer contract together in a coordinated manner and the heart beat (pulse) becomes irregular. Because the atria no longer contract normally in AFib, the blood flow in the heart can be slower than normal. This change in blood flow may cause blood clots to form. During AFib, most blood clots that originate in the heart develop in the LAA. These blood clots can break loose, travel through the bloodstream, and block a blood vessel in the brain. If this occurs, the part of the brain that is supplied by that blood vessel can become permanently damaged within minutes (also known as a stroke).

The Watchman should only be used in patients who:
- have atrial fibrillation not related to heart valve disease.
- are at increased risk for a stroke.
- are recommended for blood thinning medicines.
- are suitable for warfarin (a blood thinner also known as Coumadin).
- have an appropriate reason to seek a non-drug alternative to warfarin.

Description of Supplies/Services Required to Meet the Agency's Needs:

21mm WATCHMAN LAA Closure Device	3	EA
24mm WATCHMAN LAA Closure Device	4	EA
27mm WATCHMAN LAA Closure Device	4	EA
30mm WATCHMAN LAA Closure Device	5	EA
33mm WATCHMAN LAA Closure Device	4	EA
WATCHMAN Access System, Single Curve	3	EA
WATCHMAN Access System, Double Curve	7	EA
WATCHMAN Access System, Anterior Curve	2	EA
Clinical Case Support	1	EA

4. Statutory Authority Permitting Other than Full and Open Competition:

(X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
( ) (2) Unusual and Compelling Urgency per FAR 6.302-2;
( ) (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
( ) (4) International Agreement per FAR 6.302-4
( ) (5) Authorized or Required by Statute FAR 6.302-5;
( ) (6) National Security per FAR 6.302-6;
( ) (7) Public Interest per FAR 6.302-7;

5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):

This transaction is for the set-up of an Consignment agreement with the vendor Boston Scientific for the ongoing purchase of Watchman left atrial appendage closure devices for Fiscal Year 17 (October 1, 2016 through September 30, 2017). Watchman devices are used in the Electrophysiology Lab during emergency surgeries.

a. Only One Responsible Source (FAR 6.302-1)

Boston Scientific, Inc. is the only company capable of providing the supplies and services described in Section III above without the Veteran's Health Administration experiencing substantial duplication of cost that could not be expected to be recovered through competition and unacceptable delays in fulfilling its requirements.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:

The MEDVAMC Cardiology staff is very cognizant of products on the market for these types of electrophysiology cardiology procedures. Market research was conducted on the NAC (National Acquisition Center), GSA and the Federal Procurement Data System and determined that Boston

Scientific was open market sole-source due to being the only company to provide OCT Technology and have the compatibility to upgrade the product that the VA is currently utilizing.

7. Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:

Pricing determination was based on an existing pricing history and trends in supply and demand. Pricing was determined by the price quote submitted by the contractor and market research conducted on FPDS of preceding/previous purchase of similar product/supply by the VA.

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:

A VIP query with NAICS identifier 354510 identified 10 SDVOSB but the FBO posting on September 14, 2016 generated no responses to the solicitation. A letter from Boston Scientific concludes that items sought are proprietor, therefore no SDVOSB will be able to fulfill the requirement.
Also, the MEDVAMC Cardiology staff is very cognizant of products on the market for these types of electrophysiology cardiology procedures and currently Boston Scientific has the only Watchman device that will meet the current needs of the MEDVAMC.

9. Any Other Facts Supporting the Use of Other than Full and Open Competition: N/A

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition: N/A

11. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required: Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1

12. Requirements Certification: I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

9/29/16
Date

13. Approvals in accordance with FAR 6.304

a. Contracting Officer's Certification: (required) I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

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Date